

Notice of Allowability	Application No.	Applicant(s)	
	10/735,514	MOROS, DANIEL A.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 38-40, 50-52, 63-66 and 69-72.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20060913</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
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 SHAOJIA ANNA JIANG, PH.D.
 SUPERVISORY PATENT EXAMINER

Detailed Action

This application claims benefit of provisional application 60/432470, filed December 11, 2002. Applicant's amendment, submitted September 1, 2006, is acknowledged wherein claims 1-37, 41-49, and 53-60 are cancelled and new claims 61-72 are introduced.

Claims 38-40, 50-52, 63-66, and 69-72 are pending in this application and examined on the merits herein.

The reasons for allowance will be discussed below.

The reasons for allowance and Examiner's Amendment are as follows:

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claims 61, 62, 67, 68 are cancelled.

Authorization for this examiner's amendment was given in a telephone interview with Matthew Kelley on September 13, 2006.

Additionally, the claims are renumbered as follows:

Independent claims 38-40 are renumbered as 1-3.

Independent claims 50-52 are renumbered as 4-6.

Dependant claims 63-66 and 69-72 are renumbered and amended as follows:

63. 7. The method of claim ~~39~~ 2, wherein the composition comprises a pharmaceutically acceptable salt of the compound.

64. 8. The method of claim ~~63~~ 7, wherein the pharmaceutically acceptable salt comprises a sodium salt.

65. 9. The method of claim ~~40~~ 3, wherein the composition comprises a pharmaceutically acceptable salt of the compound.

66. 10. The method of claim ~~66~~ 9, wherein the pharmaceutically acceptable salt comprises a sodium salt.

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~~69.~~ 11. The method of claim ~~54~~ 5, wherein the composition comprises a pharmaceutically acceptable salt of the compound.

~~70.~~ 12. The method of claim ~~69~~ 11, wherein the pharmaceutically acceptable salt comprises a sodium salt.

~~74.~~ 13. The method of claim ~~52~~ 6, wherein the composition comprises a pharmaceutically acceptable salt of the compound.

~~72.~~ 14. The method of claim ~~74~~ 13, wherein the pharmaceutically acceptable salt comprises a sodium salt.

Reasons for Allowance

Currently, claims 1-14, formerly numbered 38-40, 50-52, 63-66, and 69-72, are pending in this application.

Claims 1-14, formerly numbered 38-40, 50-52, 63-66, and 69-72, have been examined on the merits herein.

The claimed method of treating Parkinson's disease and essential tremor, is not seen to be taught or fairly suggested by the prior art, as discussed below.

Applicant's amendments filed September 1, 2006 with respect to the rejection of instant claims 1-7, 10-20, 23-28, and 53-57 under 35 USC § 112, first paragraph for lacking enablement for the treatment of disorders other than Parkinson's disease and essential tremor, have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 1, 2006 with respect to the rejection of instant claims 1, 2, 8, 14, 15, 21, 27, 29, 30, and 53 under 35 USC § 102 for being anticipated by Sasso et al., have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 1, 2006 with respect to the rejection of instant claims 12, 13, 25, 26, 36, and 37 under 35 USC § 103 for being obvious over

Sasso et al., have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 1, 2006 with respect to the rejection of instant claims 1, 2, 9, 12-15, 22, 25-30, 36-37, 41, 42, 48, 49, and 54 under 35 USC § 103 for being obvious over Curry, have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 1, 2006 with respect to the objection to instant claims 31-35, 43-47, and 58 as being dependant on a rejected base claim, have been fully considered and found to be persuasive to remove the objection, as the objected claims are no longer pending.

Reasons for allowance are as follows: The claimed methods of treating essential tremor and Parkinson's disease comprising administering a diphenylbarbituate compound as claimed by the aforementioned claims are seen to be novel and non-obvious over the prior art and are directed to subject matter adequately described and enabled by Applicant's specification. For example, written description and enablement are provided by the *in vivo* therapeutic method and experimental data disclosed on pp. 28-31 of Applicant's specification. The specific structures claimed by the indicated claims are not known in the prior art to be useful for the treatment of movement disorders, and no methods of treating movement disorders by administering these

compounds have been disclosed in the prior art. The diphenyl- and mono-or di-methoxymethyl- derivatives of the disclosed structure, as well as all pharmaceutically acceptable salts of these structures, where applicable, are non-obvious over the prior art compounds known to be useful for treating movement disorders, such as phenobarbital. Therefore the indicated subject matter is allowable over the prior art

Claims 61, 62, 67, and 68 have been cancelled in the examiner's amendment set forth above.

Accordingly, Applicant's amendment submitted September 1, 2006, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner
AU 1623
9/13/06

Anna Jiang



Supervisory Patent Examiner
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